

**Remarks/Arguments**

Claims 1-4, 6-7 and 18-21 are currently pending. Claim 25 has been added.

**I. Rejections to the Specification**

The Examiner noted that the application does not contain an abstract on a separate sheet. Therefore, Applicants hereby submit an abstract of the disclosure on a separate sheet with this Response.

The Examiner noted the use of trademarks within the application. Applicants have amended the specification to assure the proper source is identified with each trademark usage within the application. No new matter, except for trademark source information, has been added by way of this amendment to the specification.

**II. Rejections Under 35 U.S.C. § 112, First Paragraph**

The Examiner rejected claims 1-24 under 35 U.S.C. § 112, first paragraph. The Examiner argued that the specification, "while being enabling for capsule or gelatin capsule for use as a dietary supplement for pregnant women and elderly patients, does not reasonably provide enablement for edible formulation or any other pharmaceutical compositions or for uses of the formulation other than dietary supplementation."

Although Applicants disagree with many of the points raised by the Examiner, the claims, as amended, narrow the scope of protection currently sought by Applicants and alleviate the Examiner's concerns regarding enablement. Support for the amendments to the claims is found at pages 11-19 of the application.

Additionally, different modes of administration of ARA are known and acceptable to a person skilled in the art. As noted by the Examiner, "[t]he relative skill of those in the art is high." It would be apparent to those skilled in the art that any edible composition, provided it does not interfere with the efficacy of the ARA, will be suitable to practice the present invention. A person skilled in the art would not be forced to turn to trial and error experimentation to utilize the methods and compositions of the present invention.

**III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejected Claims 5 and 12-24 under 35 U.S.C. § 112, second paragraph. Applicants believes the claims, as amended, overcome all of the Examiner's rejections under 35 U.S.C. § 112, second paragraph.

**IV. Rejections Under 35 U.S.C. § 102**

*A. Rejection of Claims 1-6, 8-11, 16, 17, 19-21 as anticipated by WO 96/37200.*

The Examiner rejected claims 1-6, 8-11, 16, 17, and 19-21 as anticipated by WO 96/37200 ('200). Claims 5, 8-11, 16 and 17 are no longer pending in the present application. Claims 1-4, 6, and 19-21 have been amended to depend from Claim 15, which is not anticipated by '200.

*B. Rejection of Claims 1-6, 8-10, 16, 17 and 19-24 as anticipated by WO 96/4010.*

The Examiner rejected claims 1-6, 8-10, 16, 17, and 19-24 as anticipated by WO 96/40106 ('106). Claims 5, 8-10, 16, 17 and 22-24 are no longer pending in the present application. Claims 1-4, 6, and 19-21 have been amended to depend from claim 15, which is not anticipated by '106.

*C. Rejection of claims 1-3, 6, 8, 9, 16, and 17 as anticipated by EP 409559.*

The Examiner rejected claims 1-3, 6, 8, 9, 16 and 17 as anticipated by EP 409 559 ('559). Claims 8, 9 and 16 are no longer pending in the present application. Claims 1-3 and 6 have been amended to depend from Claim 15, which is not anticipated by '559.

*D. Rejection of Claims 1-6, 9, 10, 16, 17, 19-21 as anticipated by EP 733 360.*

The Examiner rejected claims 1-6, 9, 10, 16, 17 and 19-21 as anticipated by EP 733 360 ('360). Claims 5, 9, 10, 16, and 17 are no longer pending in the present application. Claims 1-4, 6, and 19-21 have been amended to depend from Claim 15, which is not anticipated by '360.

**V. Rejections Under 35 U.S.C. § 103**

*A. Rejections of Claims 7, 12-15, 18 and 22-24 over WO 96/37200.*

The Examiner rejected claims 7, 12-15, 18 and 22-24 as being unpatentable over WO 96/37200. Claims 12-14 and 22-24 are no longer pending in this application. Claim 7 has been amended to depend from claim 15.

The Examiner went to great length (5 pages of the official action mailed June 18, 2004) in arguing that the specification of the present application did not enable the use of the present invention other than "s a dietary supplement for pregnant women and elderly patients." The Examiner argued that undue experimentation would be required of those skilled in the art to utilize the present invention for other claimed disorders. Yet, the Examiner now argues that a reference directed to retinal disease, obviates the use of ARA with respect to pregnancy, lactation and fertility (i.e., claims 15 and 18). Though Applicant disagrees with many of points raised in

the Examiner's enablement argument, if the Examiner's enablement position is correct, then her own arguments negate her present rejection under 35 U.S.C. §103. It cannot be obvious to transfer the teachings of the use of ARA for one disorder to a different disorder, if the Examiner's position stated in Section 5 of the official action is correct.

WO 96/37200 does not anticipate nor render obvious the subject matter claimed in amended claims 15 and 18, nor the amended claims depending therefrom.

*B. Rejection of Claims 7, 11-15 and 18 over WO 96/40106.*

The Examiner rejected claims 7, 11-15 and 18 as being unpatentable over WO 96/40106. Claims 11-14 are no longer pending in this application. Claim 7 has been amended to depend from claim 15.

As explained in section VA above, the Examiner's argument of obviousness with respect to claims 15 and 18 is completely at odds with the Examiner's enablement rejections at pages 3-7 of the official action. Under the Examiners present position regarding the state of the art WO 96/40106, directed to a method for treating neurological disorders, cannot obviate the use of ARA as claimed in amended claims 15 and 18 nor the claims depending therefrom.

*C. Rejection of claims 4, 5, 7, 10-15, 18-24 over EP 409 559.*

The Examiner rejected claims 4, 5, 7, 10-15 and 18-24 as being unpatentable over EP 409 559 ('559). Claims 5, 10-14 and 22-24 are no longer pending in this application. Claims 4, 7 and 19-21 have been amended to depend from claim 15.

As explained in section VA above, the Examiner's present obviousness argument with respect to claims 15 and 18 is negated by the Examiner's enablement arguments at pages 3-7 of the official action. Hence, EP 409 559, does not anticipate or obviate the use of ARA as claimed in amended claims 15 and 18 of the present application, as well as the claims depending therefrom.

*D. Rejection of claims 7, 8, 11-15 18, 22-24 over EP 733 360.*

The Examiner rejected claims 7, 8, 11-15, 18 and 22-24 as unpatentable over EP 733 360. Claims 8, 11-14, and 22-24 are no longer pending in the present application. Claim 7 has been amended to depend from claim 15.

As explained in section VA above, the Examiner's present obviousness argument with respect to claims 15 and 18 is negated by the Examiner's enablement arguments at pages 3-7 of the official action. Hence EP 733 360 does not anticipate or obviate the use of ARA as claimed in amended claims 15 and 18 of the present application nor the claims depending therefrom.

*E. Rejection of Claims 1, 2 6-9, 12-15, 16, and 18 over WO 98/16119*

The Examiner rejected claims 1, 2, 6-9, 12-15, 16 and 18 as unpatentable over WO 98/16119 ('119). Claims 8-9, 12-14 and 16 are no longer pending in this application. Claims 1, 2 and 6-7 have been amended to depend from claim 15.

Claim 15, as amended, is directed to a non-human mammal. WO 98/16119 does not teach or suggest administering ARA to non-human mammals. Additionally, WO 98/16119 does not suggest the use of ARA to non-human mammals that are pregnant or lactating in accordance with amended claim 15. Furthermore, WO 98/16119 does not suggest the administration of ARA to promote lactating or fertility in non-human mammal, in accordance with amended claim 18.

*F. Rejection of claims 3-5, 10 and 19-21 over WO 98/16119 in view of Makrides, et al.*

The Examiner rejected claims 3-5, 10 and 19-21 as unpatentable over WO 98/16119 in view of Markrides et al. Claims 5 and 10 are no longer pending in the present application. Claims 3-4 and 19-21 have been amended to depend from claim 15.

Claim 15, as amended, is directed to a non-human mammal. As explained in section V E above, WO 98/16119 does not teach or suggest administering ARA to non-human mammals. Markrides et al. does not overcome the deficiencies of WO 98/16119. There is no suggestion in either of these prior art references to using ARA in a way taught by amended claims 15 and 18.

In view of the amendments and remarks enclosed herein, Applicant believes that the present claims are patentable over the rejections raised by the Examiner. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

**McDonnell Boehnen  
Hulbert & Berghoff**

Dated: December 20, 2004

By: 

Alison J. Baldwin  
Reg. No. 48,968

## **Appendix**